PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Effects of telephone health mentoring in community-recruited chronic obstructive pulmonary disease on self-management capacity, quality of life and psychological morbidity: a randomised controlled trial
AUTHORS	Walters, Julia; Cameron-Tucker, Helen; Wills, Karen; Schüz, Natalie; Scott, Jenn; Robinson, Andrew; Nelson, Mark; Turner, Paul; Wood-Baker, Richard; Walters, E Haydn

VERSION 1 - REVIEW

REVIEWER	Mike Morgan No COI
REVIEW RETURNED	07-May-2013

GENERAL COMMENTS	This study describes a randomised controlled trial of the benefits of telephone delivered health mentoring in mild to moderate COPD. The mentoring is delivered remotely by health professionals trained in behaviour change. The control group also received telephone calls but with no evident intervention. The outcome measures were one generic quality of life measure and one disease specific questionnaire. The trial did not reach its calculated sample size but nevertheless showed no difference in the health status between groups though self-management capacity increased in the intervention group and anxiety and coping skills improved in both groups. This is an important area where good studies are required. In this case the authors are to be commended for exploring an area with appropriate methodology. What is particularly attractive is their quantification of the degree of behaviour change therapy that was received by the patients. The study is weakened by the failure to achieve the expected sample size though there does not appear to be any major signal from the intervention in the chosen outcomes. I think that this area is particularly complicated by the expectation that behaviour change can occur in patients who have mild to moderate disease and therefore will have little in the way of motivation to change. In the absence of symptoms this may be an expectation too far in terms of the relatively blunt instruction of the primary outcome measures. Alternatively as the authors suggest any intervention including the control arm may improve the situation. The patients in this study are a relatively moderate group (GOLD stage 2) and

	would not have had significant expressed sufficient disability to enter a rehabilitation programme (MRC score <3). The authors could argue the impact of behaviour change suggested in this group would not be so well received in the absence of hard symptoms. In all, this is an otherwise sound study from a respected group who have explored this area in the past. Specific points: 1. There is clearly no specific exercise advice within this programme. I wonder if the authors think, in retrospect, whether being more proscriptive in the area might have been helpful, certainly exercise training (ref. Toshima) is a necessary part of formal pulmonary rehabilitation. 2. Health monitoring is only one component of a supported self management system (Chronic Care Model) where supportive infrastructure is also required to show benefit, is there any suggestion that additional components to the support structure would have been desirable? 3. The health mentor training seems to have been well done Do the authors feel the solitary nature of the advice, without any group interaction, might have lacked effect? 4. The primary outcome questionnaires (SF36 and the St Georges' respiratory questionnaire) are fairly blunt instruments with regard to self management training, it is unlikely that either would be very sensitive for the intervention. Did you consider more sensitive questionnaires like the chronic respiratory questionnaire or the CAT as alternatives? As you point out the results in the usual care group seem to improve, rather than deteriorate as you might expect over 12 months. Clearly the control arm seems to be improved by the limited intervention. This is an important study which is well conceived and delivered, however slightly disappointing in its outcome because of the failure to reach the sample size and also because of the negative effect on the chosen primary outcomes. In hindsight of course it would be possible to see that different outcome measures may have had a different result. While not changing the world this paper adds another piece of useful knowledge to the puzzle of self management training in COPD.

REVIEWER	Sarah Dennis, Senior Research Fellow, Centre for Primary Health

	Care & Equity, University of New SOuth Wales, Australia. I have no competing interests
REVIEW RETURNED	11-May-2013

GENERAL COMMENTS	Patient recruitment – GPs identified the patients and then invited those interested to come into the practice for screening. Who performed the spirometry in the practice (GP or PN) and had they had training for the study in order to do this accurately? Page 9 – the nurses providing the coaching are referred as community health nurses and then community nurse health mentors. Please can you chose a title and stick with it – when I saw the term community nurse health mentors I thought they were extra nurses mentoring those providing the coaching. How many community health nurses took part in the study and how were they recruited or employed by university etc? I know you cannot do anything about it now, but I do think it would have been possible to have blinded the research officers collecting the data. We have managed to keep ROs blind to the allocation in a similar study. The numbers in the flow chart need to be double checked as they didn't quite add up. In the usual care group, 92 patients were allocated to UC and 2 withdrew leaving 90 to receive the intervention, then a further 10 were lost to FU leaving 80. However, the coaching group starts with 90 and then 11 withdraw so that 79 receive the intervention. A further 14 are lost to follow-up yet 74 remain in the analysis, should it be 65? Overall the results are consistent with other trials and systematic reviews of self-management for COPD.

REVIEWER	I have no conflicts of interest. Dr Victoria Allgar Senior Lecturer Hull and York Medical School
REVIEW RETURNED	20-May-2013

THE STUDY	The length of time since diagnosis may impact on the findings. Also, over the 12 month period other factors may have impated on Qol, which were not addressed in the findings.
RESULTS & CONCLUSIONS	The study is slightly powered based on the sample size calculation; this is particularly the case at 12 months. The power calculation was based on detecting a large difference in QoL between groups, which may have been ambitious. There needs to be more information on the intervention e.g. timing, number of calls etc...This is particularly the case for the number of calls which ranged from 1-17 in the intervention group. The control groups actually had more, albeit shorter calls, that the intervention group, based on median scores. This could be controlled for in the analysis. There was no statistical adjustment for multiple testing, particularly for the large number of outcome measures shown in Table 3.

REVIEWER	
REVIEW RETURNED	21-May-2013 Jacob K. Sont, PhD, associate professor Department of Medical Decision Making, J10-86 Leiden University Medical Center P.O. Box 9600 NL-2300 RC LEIDEN The Netherlands I state that I have no competing interests

THE STUDY	It seems that at least the description of the analysis could be improved. It is unclear whether or how baseline observations and time were included in the model. Were baseline measurements of the outcome under study as dependent variables or were they included as covariates. Was time included as a continuous variable? If so, this only allows to test whether there is an (inceasing) change wth time. However, it is not the most efficient way to test whether there is a more acute change in outcome. The best way to analyse this data is probably to include outcomes at 6 and 12 mo as dependent variable adjust for their baseline levels.
RESULTS & CONCLUSIONS	Since I have some problems with the analysis it is uncertain whether the current results answer the research question, however, the potentially do. Although the information in table 2 and 3 is relevant, the main outcomes could be presented in a figure.
GENERAL COMMENTS	This is a well conducted study and well written paper. My main concerns are about the description of the analysis and the presentation of the results. Therefore, it is unclear whether the authors over- or underinterpret their data.

REVIEWER	Professor Christine McDonald Director, Department of Respiratory and Sleep Medicine Austin Health Heidelberg, Vic. 3084 Australia No COI relating to this paper.

	Advisory Board Membership: Novartis, Pfizer, Boehringer Ingelheim, GSK. Funded scientific presentations Novartis, Boehringer Ingelheim. ERS ASM attendance funded by Nycomed (2011).
REVIEW RETURNED	30-May-2013

GENERAL COMMENTS	The literature regarding the value of disease management /self management programs in COPD continues to be unclear. This study adds to the literature by demonstrating little extra benefit of health mentoring over and above regular phone calls without health mentoring in patients with COPD and moderate-severe airflow obstruction. The design of the study seems appropriate for a primary care study of this type. However, there are a number of issues. The response rate is low-as with many such studies. Are lung function results available for the group who did not respond (eg from GP case notes) in order to determine whether the group studied may be representative of the whole? Could, for example look at what percentage of the studied group had prior lung function and compare with results for those who did not respond (if any available) [given prior Ethics approval]. The group studied is stated to have moderate to severe COPD, but only 20% had oral corticosteroids in previous year and only a tiny per cent (or none in usual care) had had a hospital admission in previous year. The mean MRC score was only 2.5 or so for both groups. These are certainly towards the milder end of the COPD spectrum, and thus the potential for noticeable improvements may be less. I note this is a less severe group than was studied in the authors' previous study of health mentoring. Point of clarification: who are the community nurses? I think these are from community health centres, but this is not stated.

VERSION 1 – AUTHOR RESPONSE

Reviewer M Morgan.
1. There is clearly no specific exercise advice within this programme. I wonder if the authors think, in retrospect, whether being more proscriptive in the area might have been helpful, certainly exercise training (ref. Toshima) is a necessary part of formal pulmonary rehabilitation.
Response: 1. The health mentor intervention aimed to promote health behavior change most relevant for the individual with COPD, i.e. to be patient-centred, in a population with moderate or severe COPD. We accept that specifying an action plan for walking for each participant might have had different results. A current study is investigating this intervention. A comment on this has been added to the discussion; "The health mentor intervention aimed to promote health behavior change most relevant for the individual with COPD, i.e. to be patient-centred, however had we included an action plan for walking for each participant the results might have been different".

2. Health monitoring is only one component of a supported self management system (Chronic Care Model) where supportive infrastructure is also required to show benefit, is there any suggestion that additional components to the support structure would have been desirable?
Response: 2. Of the other aspects of the chronic care model; community, the health system, delivery system design, decision support and clinical information systems, we did not add any other model input. However, health system support through service item payments to GPs for chronic disease care and coordination were in place in the Australian primary health care system at the time of the study.
3. The health mentor training seems to have been well done Do the authors feel the solitary nature of the advice, without any group interaction, might have lacked effect?
Response: 3. We agree the individual delivery of mentoring means the vicarious experience that can occur in a group was not possible. However, telephone delivery can increase the reach of an intervention to those who are not able to access a group especially in a rural setting such as ours or who would not chose a group format..

4. The primary outcome questionnaires (SF36 and the St Georges' respiratory questionnaire) are fairly blunt instruments with regard to self management training, it is unlikely that either would be very sensitive for the intervention. Did you consider more sensitive questionnaires like the chronic respiratory questionnaire or the CAT as alternatives? As you point out the results in the usual care group seem to improve, rather than deteriorate as you might expect over 12 months. Clearly the control arm seems to be improved by the limited intervention.
Response: 4. There was an attention effect of the study on the control group, which may have reduced the difference due to the intervention. We agree that the suitability of the instruments SF36 to detect effects of self-management training is not ideal. The SGRQ is a frequent choice in studies of rehabilitation and self-management as a respiratory specific measure, which was the reason for its use, although we did consider using the CRQ. At the time of study development, the CAT tool was not published.

Reviewer: Sarah Dennis,
1. Patient recruitment – GPs identified the patients and then invited those interested to come into the practice for screening. Who performed the spirometry in the practice (GP or PN) and had they had training for the study in order to do this accurately?
Response: 1. Study research officers performed the spirometry and received training and quality control. The results have been published in reference 30, Walters JA, Walters EH, Nelson M, Robinson A, Scott J, Turner P, et al. Factors associated with misdiagnosis of COPD in primary care. Prim Care Respir J. 2011 Jun. 17;20(4):396–402. This has been added to methods "Study research officers performed the spirometry and received training and quality control feedback from researchers (JW, RWB)."

2. Page 9 – the nurses providing the coaching are referred as community health nurses and then community nurse health mentors. Please can you chose a title and stick with it – when I saw the term community nurse health mentors I thought they were extra nurses mentoring those providing the coaching.
Response: 2. We apologise for any confusion in terminology and have consistently used the term "community health nurses".

3. How many community health nurses took part in the study and how were they recruited or employed by university etc?
Response: 3. Community health nurses were invited to participate in the study by researchers with the agreement of the state community health body by whom they were employed. Thus they were 'volunteers' although the intervention was delivered during work time and formed part of their recognized case load. We have included the number of health mentors in the methods.

“Community health nurses employed by state community health services (n=31) were trained as health mentors (17) and received ongoing support during the study, via a resource manual and through regular meetings with each other facilitated by the trainers”.

4. I know you cannot do anything about it now, but I do think it would have been possible to have blinded the research officers collecting the data. We have managed to keep ROs blind to the allocation in a similar study.
Response: 4. Research officers were not involved with allocation of participants to groups. However, we felt it would not have been possible to maintain blinding of research officers during interactions with patient participants.

5. The numbers in the flow chart need to be double checked as they didn’t quite add up. In the usual care group, 92 patients were allocated to UC and 2 withdrew leaving 90 to receive the intervention, then a further 10 were lost to FU leaving 80. However, the coaching group starts with 90 and then 11 withdraw so that 79 receive the intervention. A further 14 are lost to follow-up yet 74 remain in the analysis, should it be 65?
Response:
5. Study flow chart: we have clarified the numbers of withdrawals and follow up in the intervention group. The number that was lost to follow up was 5 (2 deaths, 2 withdrew). The other 9 early discontinuers attended for follow up. Figure 1 has been amended to show this.

Reviewer: Dr Victoria Allgar
1. The length of time since diagnosis may impact on the findings. Also, over the 12 month period other factors may have impacted on Qol, which were not addressed in the findings.
Response: 1. We do not feel that length of time as reported by the participant is likely to affect outcomes, although severity of airflow obstruction might so adjustment was made for this in analyses using FEV1 % predicted.

2. The study is slightly powered based on the sample size calculation; this is particularly the case at 12 months. The power calculation was based on detecting a large difference in QoL between groups, which may have been ambitious.
Response: 2. In retrospect, the sample size calculation was based on a larger effect size using SGRQ than was achieved. Combined with logistic issues that reduced recruitment the study had lower power than was intended.

3. There needs to be more information on the intervention e.g. timing, number of calls etc...This is particularly the case for the number of calls which ranged from 1-17 in the intervention group. The control groups actually had more, albeit shorter calls, that the intervention group, based on median scores. This could be controlled for in the analysis.
Response: 3. As we state and is shown in the Mentor Resource book in Appendix 1, community nurses were asked to follow a schedule for calls as follows:
“Months 0-4: One-call to make appointment for initial telephone mentoring session. One initial telephone mentoring session.
One call weekly for 5 weeks, once action plan is set (i.e. 5 calls in 5 weeks)
Then, one call fortnightly for 8 weeks (i.e. 4 calls in 2 months)
Months 5-8: Follow up calls
One call monthly for 3 months (i.e. 3 calls in 3 months)
Months 9-12: Follow up calls
One call every 2nd month (i.e. 3 calls in 6 months).”
Community health nurses varied in adherence to the schedule.
The number of calls recorded per participant (median 7 range 1-17) differed from calls logged online (median 9.5 IQR 8) due to some recording failures. This is very similar to the number of calls to usual

care participants, made to control for the “attention effect” of contacts. However we confirmed that these calls did not deliver any intervention elements and were brief.

4. There was no statistical adjustment for multiple testing, particularly for the large number of outcome measures shown in Table 3.
Response: 4. This was an exploratory, rather than definitive, study. The ramifications of Type 1 errors are therefore low. We are interested in identifying potential areas for further research in chronic disease management.

Reviewer: Jacob K. Sont

1. It is unclear whether or how baseline observations and time were included in the model. Were baseline measurements of the outcome under study as dependent variables or were they included as covariates.
2. Was time included as a continuous variable? If so, this only allows to test whether there is an (inceasing) change wth time. However, it is not the most efficient way to test whether there is a more acute change in outcome.
3. The best way to analyse this data is probably to include outcomes at 6 and 12 mo as dependent variable adjust for their baseline levels.
Since I have some problems with the analysis it is uncertain whether the current results answer the research question, however, they potentially do.
Response: Points 1-3:
The description of linear mixed models has been expanded and is now more specific. It should now be clear that time was included as a categorical variable denoting visit number and includes baseline as the first visit. We modeled the intervention effect over time by including a treatment by time (visit) interaction. Regression coefficients thus indicate change per 6-month visit. We considered this to be more relevant than treating time as continuous and interpreting change per month. Baseline levels were similar in the two groups and we consider the longitudinal model to be the most appropriate.

4. Although the information in table 2 and 3 is relevant, the main outcomes could be presented in a figure.
Response: We wished to present the results as fully as possible for readers to understand the population and changes in outcomes, so we chose to use tabular form to achieve this. In order to reduce space, we have presented some secondary outcomes in an appendix Table 4.

Reviewer: Professor Christine McDonald.
1. The response rate is low-as with many such studies. Are lung function results available for the group who did not respond (eg from GP case notes) in order to determine whether the group studied may be representative of the whole? Could, for example look at what percentage of the studied group had prior lung function and compare with results for those who did not respond (if any available) [given prior Ethics approval].

Response: 1. Nearly 50% of patients who received an invitation and information from their general practice replied to researchers; and if refusals and exclusions on criteria are added the positive responder rate was 29%. This is in line with other primary care recruited studies in COPD such as Zwar 2012 which had a 45% response rate and Bunker 2009 with a 29% response rate in the group receiving an intervention.
(Zwar NA, et al. Care of patients with a diagnosis of chronic obstructive pulmonary disease: a cluster randomised controlled trial. Med J Aust. 2012;197(7):394–8.
Bunker J, et al. Feasibility and efficacy of COPD case finding by practice nurses. Aust Fam Physician. 2009 38(10):826–30.)
We did not have ethics approval to review the GP records for all patients who were invited, as they

had not provided consent to participate. Spirometry performed by research officers, established that 31% of responders did not meet the diagnostic criteria for COPD and it is likely that the diagnosis for many patients had not been based on spirometry (Walters JA, et al. Factors associated with misdiagnosis of COPD in primary care. Prim Care Respir J. 2011;20(4):396–402).

2. The group studied is stated to have moderate to severe COPD, but only 20% had oral corticosteroids in previous year and only a tiny per cent (or none in usual care) had had a hospital admission in previous year. The mean MRC score was only 2.5 or so for both groups. These are certainly towards the milder end of the COPD spectrum, and thus the potential for noticeable improvements may be less. I note this is a less severe group than was studied in the authors' previous study of health mentoring.
Response: 2. All participants had confirmed moderate (62%) or severe COPD on spirometry, recruited in primary care and most were not under specialist care. 20% had received oral corticosteroid treatment in the previous 12-months for an acute exacerbation (50% had received antibiotics). This is in line with similarly recruited populations. For example in moderate or severe COPD (van Wetering 2010), the prior 12 months exacerbation rate was mean 1.1 (SD 1.4). A survey in GP patients with moderate COPD (Jones 2008) found the mean number of courses of steroids in the previous 12 months was 0.7 (SD 1.4).
Refs;
van Wetering et al Short- and long-term efficacy of a community-based COPD management programme in less advanced COPD: a randomised controlled trial. Thorax. 2010;65(1):7–13.
Jones R, et al. Accuracy of diagnostic registers and management of chronic obstructive pulmonary disease: the Devon primary care audit. Respir Res. 2008;9:62.

3. Point of clarification: who are the community nurses? I think these are from community health centres, but this is not stated.
Response:
3. Community nurses are working for community health services, including some who are based in community health centres. This has been clarified in Methods. "Community health nurses employed by state community health services (n=31) were trained as health mentors (17),"